donors, confirmed the observed induction of genes by PTx and extended the data by showing specificity for PTx in comparison to *E. coli* lipopolysaccharide and *B. pertussis* lipo-oligosaccharide. Statistical analysis, with a false/discovery rate (FDR) of 2% and an up-regulation by a ratio > 4 of PTx against any of the other exposures, indicated six genes that were significantly up-regulated by PTx: IFNG, IL-2, XCL1, CD69, CSF2 and CXCL10. Increased levels of the secreted proteins in the supernatants of PTx-treated MoDCs, corresponded to the up-regulated genes (IFNG, IL-2, XCL1, and CXCL10), confirming the effects of PTx on these genes. Although further evaluation is required, these genes have the potential to control the safety of pertussis vaccines.

The Future of Non-human Primates in the Development of Biopharmaceuticals

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Due to the characteristics unique to monoclonal antibodies (MAbs) and other biotech products, non-human primates (NHP) are often assumed to be the only relevant species to evaluate safety and efficacy of MAbs. However, the scientific value of NHP in MAb development has never been adequately established, and has been debated since it became clear that the non-clinical safety programmes used for small molecule therapeutics would not be appropriate for MAbs. In this retrospective analysis, we studied the value of using NHP to evaluate the safety and efficacy of these products. To do this, we had unique access to the drug registration files of all MAbs marketed in the European Union. Inadequately justifying the use of NHP as a primary non-clinical species and the use of study designs that were considered ineffective led to a needless increase of NHP use. The value of NHP in non-clinical assessment was further limited by immunogenicity. But more importantly, NHP do not stand out as a predictive model because MAbs primarily exert their expected pharmacological effect. Nevertheless, their use continues to increase. There is an urgent need for a reevaluation of the need for routine studies with NHP to develop MAbs.

Inconsistencies in Data Requirements of EU Legislation Involving Tests on Animals

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Present and future European Union (EU) legislation on the protection of animals used for scientific purposes (*Directives 86/609/EEC* and *2010/63/EU*) requires that alternative methods have to be used instead of animal tests wherever they are available. Unfortunately, this provision is not implemented to its full extent when it comes to risk assessment of chemicals and new products prior to their authorisation and placing on the market in the EU. In this study, the Animal Welfare Academy of the German Animal Welfare Federation screened data requirements of relevant EU law regarding chemicals (REACH), biocides, pesticides and food safety (Novel Food), and found that data requirements as part of the risk assessment do not always reflect the state-of-the-art of science and technology. Most of the data requirements we investigated still include testing on animals for many toxicological endpoints, even though